

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MM/03154/PCT	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2004/011349	International filing date (day/month/year) 06.10.2004	Priority date (day/month/year) 10.10.2003	
International Patent Classification (IPC) or national classification and IPC B01L3/14			
<p>Applicant AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO et al.</p>			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 1 sheets, as follows:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>			
Date of submission of the demand 03.08.2005	Date of completion of this report 26.01.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Tiede, R Telephone No. +31 70 340-1090		



10/575180

## **INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.  
PCT/EP2004/011349

AC2006-01910 10 APR 2006

**Box No. I Basis of the report**

- With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
    - This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
      - international search (under Rules 12.3 and 23.1(b))
      - publication of the international application (under Rule 12.4)
      - international preliminary examination (under Rules 55.2 and/or 55.3)
  - With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

**1-10** as originally filed

## **Claims, Numbers**

4-19 as originally filed  
1-3 received on 11.08.2005 with letter of 03.08.2005

## **Drawings, Sheets**

1/3-3/3 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:  
 the description, pages  
 the claims, Nos.  
 the drawings, sheets/figs  
 the sequence listing (*specify*):  
 any table(s) related to sequence listing (*specify*):

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).  
 the description, pages  
 the claims, Nos.  
 the drawings, sheets/figs  
 the sequence listing (*specify*):  
 any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes:	Claims	3,5-8
	No:	Claims	1,2,4,9-19
Inventive step (IS)	Yes:	Claims	3
	No:	Claims	1,2,4-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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(SEPARATE SHEET)**

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**Re Item V.**

- 1 The following documents are referred to in this communication:
- D1 : US 5 663 051 A (VLASSELAER PETER VAN) 2 September 1997 (1997-09-02)  
 D2 : US 6 197 579 B1 (HASAN SHIRIN W ET AL) 6 March 2001 (2001-03-06)  
 D3: WO 02/089725 A (NEXELL THERAPEUTICS INC ;JULIAR RENA (US);  
     ETTEFAGH GUILTY (US)) 14 November 2002 (2002-11-14)  
 D4: US 2002/185457 A1 (SMITH EMERY ET AL) 12 December 2002 (2002-12-12)

**2 INDEPENDENT CLAIM 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
 Document D2 discloses (the references in parentheses applying to this document):  
 A disposable container for centrifugation comprising a container with a removable lid (figure 1; columns 5 and 6 and fig. 4 and 6a), said lid comprising three opening with canulas entry ports (72, 76, 77) and a removable stopper (col. 6, line 13; col. 9, line 66) for a vent channel suitable to control venting. Furthermore it discloses that said length of one of said canulas can be varied in length (col. 6, line 33) and in particular it has a length equal in height of the container (fig. 6c and col. 10, lines 1-9).
- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not inventive in the sense of Article 33(2) PCT.  
 Document D1 discloses (the references in parentheses applying to this document):  
 A disposable container for centrifugation comprising a container with a lid (figure 6; column 11), said lid comprising three opening with canulas (92, 78, 82, "luer ports") and a removable stopper (86) for a vent channel, said cap is suitable to control the entry and exit of air. Furthermore, one of said canulas has a length at least equal to that of the height of said container. The device is suitable for control of entry and exit of air and the sterile handling of samples without sterile hoods.
- 2.3 D1 differs from claim 1 in that it does not disclose a removable lid in combination with the embodiment of fig. 6. However, removable lids are a well known and a common

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feature of container for centrifugation (see for example in D1 with respect to embodiments relating to fig. 1-5 and 8), in fact it must be regarded as a commonly known design feature/possibility of such containers. Such a feature can only be regarded as inventive, if the removability of said lid presents unexpected effects or properties. However, no such effects or properties are indicated in the application. Hence, no inventive step is present in the subject-matter of claim 1.

**3 DEPENDENT CLAIMS 2, 4, 5-19**

Dependent claims 2, 4, 5-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see citations as given in the International Search Report).

**4 DEPENDENT CLAIM 3**

The combination of the features of dependent claim 3 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:  
Subject-matter of claim 3 differs from D1 in that a tap is foreseen at the vent port.

Said vent port solves the problem to simplify operation under sterile conditions (page 2).

Although the problem is well known, D1 does not suggest or imply taps at the vent port in order to regulate ventilation of said container.

Subject-matter of claim 3 is therefore new and inventive (Article 33 PCT).

**Re Item VIII.**

5 Claims 5-7, 9 relate to features of a needle and a syringe to be used with a container of claim 1. However, according to the wording of claim 1 neither said needle nor said syringe are part of the claimed container - the container is simply suitable to be used

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with a needle/syringe. This leaves the reader in doubt as to the meaning and scope of claims 5-7 and eventually also claim 1. Claims 1, 5-7 are therefore not clear (Article 6 PCT).

- 6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

AP20 Rec'd PCT/PTO 10 APR 2006

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## CLAIMS

1. A disposable container (1) for centrifuging and treating a fluid biological material, said container (1) being provided with an open top end and a closed bottom end (16), characterized in that said top end is provided with a <sup>↔</sup><sub>↔</sub> lid (2) having:
  - a) a first opening (3) passed through by a first cannula (4) which can be connected operationally to the external environment in order to control the entry and exit of air in conjunction with the transfer of a fluid biological material into or from said container;
  - b) a second opening (7) passed through by a second cannula (8) which can be accessed by a hollow needle (9) in order to transfer a fluid biological material into or from said container (1) through said hollow needle (9);
  - c) a third opening (11) passed through by a third cannula (12) operationally connected to an attachment (22) able to receive and accommodate one end of a syringe (18) in order to transfer a fluid biological material into or from said container (1) through said third cannula (12); and
  - d) the top end (5, 24) of said first cannula (4) is provided with a removable stopper (20, 25) for controlling the entry and exit of air in conjunction with the transfer of a fluid biological material into or from said container.
2. A container (1) according to Claim 1, characterized in that said top end (5) of said first cannula (4) is shaped so as to receive and accommodate one end (19) of a syringe (18) or an adaptor (23) fitted onto said end (19) of said syringe (18) in order to transfer a fluid biological material into or from said container (1) through said first cannula (4).
3. A container (1) according to Claim 2, characterized in that a tap (6) is arranged between said top end (5) and said first cannula (4).

<sup>↔</sup><sub>↔</sub> removable<sup>↔</sup><sub>↔</sub> whose length is at least equal to the height of said container (1);

## INTERNATIONAL SEARCH REPORT

International Application No  
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**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 B01L3/14

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 B01L A61J A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 663 051 A (VLASSELAER PETER VAN) 2 September 1997 (1997-09-02) column 11, line 3 - column 12, line 8; figure 6 ----- US 6 197 579 B1 (HASAN SHIRIN W ET AL) 6. March 2001 (2001-03-06) column 2, line 43 - column 3, line 9; figures 1,4,6 column 5, line 5 - column 7, line 6 column 9, line 29 - column 11, line 2 -----	1,2,4-7
X	WO 02/089725 A (NEXUM THERAPEUTICS INC ;JULIAR RENA (US); ETTEFAGH GUITY (US)) 14 November 2002 (2002-11-14) page 1 - page 5; figures 4,6-9 -----	1,2,5-7, 9-19
A		1,2,4, 9-19

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the International search

25 January 2005

Date of mailing of the International search report

07/02/2005

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## INTERNATIONAL SEARCH REPORT

International Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/185457 A1 (SMITH EMERY ET AL) 12 December 2002 (2002-12-12) paragraphs '0006! - '0011! paragraphs '0023! - '0043!; figures 1-4 -----	1, 2, 9-19
A	FR 2 630 927 A (RHONE POULENC CHIMIE) 10 November 1989 (1989-11-10)  page 3, line 3 - page 3, line 13; figures 1, 4 page 4, line 33 - page 5, line 34 page 7, line 14 - page 7, line 23 -----	1, 2, 10-15, 17, 18
A	US 5 096 573 A (BERMUDEZ WILFRED) 17 March 1992 (1992-03-17) column 4, line 29 - column 4, line 42; figure 5 -----	1
A	WO 02/09636 A (STUMMER SONITA) 7 February 2002 (2002-02-07) page 13, line 26 - page 16, line 17; figures 4-6 -----	6-8
A	GB 648 522 A (BAXTER LABORATORIES INC) 3 January 1951 (1951-01-03) the whole document -----	1-19

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/EP2004/011349

Patent document cited in search report	Publication date		Patent family member(s)	Publication date	
US 5663051	A 02-09-1997		US 5474687 A US 5646004 A US 5840502 A US 5648223 A AU 707878 B2 AU 1415097 A CA 2239729 A1 EP 0958046 A1 JP 2000502892 T WO 9721488 A1 AT 186398 T AU 700743 B2 AU 3502595 A CA 2198607 A1 DE 69513188 D1 DE 69513188 T2 DK 778944 T3 EP 0778944 A1 ES 2140705 T3 HK 1013862 A1 JP 10508190 T JP 3397795 B2 NZ 292756 A WO 9607097 A1 US 5789148 A		12-12-1995 08-07-1997 24-11-1998 15-07-1997 22-07-1999 03-07-1997 19-06-1997 24-11-1999 14-03-2000 19-06-1997 15-11-1999 14-01-1999 22-03-1996 07-03-1996 09-12-1999 06-07-2000 01-05-2000 18-06-1997 01-03-2000 05-10-2000 18-08-1998 21-04-2003 28-10-1998 07-03-1996 04-08-1998
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US 5096573	A 17-03-1992		NONE		
WO 0209636	A 07-02-2002		AU 7957001 A WO 0209636 A1	13-02-2002 07-02-2002	
GB 648522	A 03-01-1951		NONE		